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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DOWELL, PAUL THOMAS	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/520,745	CASIMIR, COLIN MAURICE	
	Examiner	Art Unit	
	Paul Dowell	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 43-67 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 43-67 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 43-67 are pending.

It is noted that claims 47, 54 and 55 have not been assigned to any of the group put forth herein below for the following reasons:

Claim 47 recites, "A method as in claim 43 wherein ***the growth factor*** is membrane-bound stem cell factor" (emphasis added). However, claim 43 does not recite a growth factor and therefore it is unclear as to what claim 47 is drawn.

Claim 54 recites, "A method as in claim 43 wherein the modified cell binding activity allows ***the viral peptide*** to bind to a target cell" (emphasis added). However, claim 43 does not recite a viral peptide and therefore it is unclear as to what claim 54 is drawn. Claim 55 depends from claim 54.

The instant claims may be assigned to a group once clarification is obtained.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 43-46, 48, 50-53 and 56, drawn to a viral particle having a modified cell binding activity and a method of making said viral particle comprising the recited steps.

Group II, claim(s) 43 and 58-67, drawn to a preparation of viral particles incorporating a passenger peptide binding moiety and a method of making said viral particles, said method comprising a step of enriching the titre of said viral particles.

Group III, claim(s) 49, drawn to a method of treating, preventing or diagnosing a disease or disorder comprising the step of employing a bioactive agent.

Group IV, claim(s) 57, drawn to a method for preparing an enriched population of a target cell type comprising the recited steps.

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The technical feature linking groups I-IV appears to be a viral particle having a modified cell binding activity. However, said technical feature is taught by Cosset et al **(Journal of Virology:69:6314-6322, 1995, IDS)** to lack novelty or inventive step because Cosset teaches a method of making a retroviral particle exhibiting modified cell binding activity. Specifically, Cosset teaches a method of making a retroviral particle by transfecting a viral packaging cell (TELCeB6 cells) with a nucleic acid encoding both wild type retroviral genes and a nucleic acid encoding a chimeric epidermal growth factor receptor (EGFR) binding peptide-MLV surface protein (SU) gp70 viral envelope protein (page 6315, col. 1, paragraphs 1 and 2). Cosset teaches that the resultant viral particle exhibits modified cell binding activity as evidenced by said viral particle binding to cell types expressing EGFR while viral particles with an unmodified non-chimeric MLV surface protein (SU) gp70 envelope do not bind to cell types expressing EGFR (page 6316, col. 1 to page 6317, col. 2, line 5). Therefore, the instant technical feature of groups I-IV does not make a contribution over the prior art.

Furthermore, while groups I and II are related in being drawn to viral particles and methods of making said viral particles, they are patentably distinct because the method of group II comprises a step of enriching the titre of viral particles, a step that is not required for the method of group I.

Furthermore, while groups III and IV are related as methods of using the same viral particles, they are patentably distinct because they are drawn to methods comprising distinct steps with distinct goals. For example, group IV is drawn to a method for preparing an enriched population of a target cell type comprising a step of separating viral particles bound to target cells from a larger population of cells, a step that is not required for the method of treating, preventing or diagnosing a disease or disorder of group IV.

Furthermore, groups I, II and groups III, IV are related as product (groups I, II) and process of use (groups III, IV). The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the viral particles of groups I and II can be used in the materially different processes of a method of treating (group III) and a method of preparing an enriched population of target cell type (group IV). Further, the methods of groups III, IV comprise unique steps that are not required for the methods of groups I, II. As such, groups I, II are patentably distinct each from groups III, IV.

A search and examination of more than one invention as defined above would unduly burden the Office. Each of the inventions requires a different search of the art and concerns separate considerations of patentability. For example, the subject matter of many of the inventions is not largely co-extensive as the inventions are related to distinct methods. Therefore, restriction as defined above is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Dowell whose telephone number is (571)272-5540. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Paul Dowell
Art Unit 1632